

K041459

JUL - 1 2004

Medtronic Emergency Response Systems
LIFEPAK® 12 Defibrillator/Monitor -Pulse Oximetry
510(k) Premarket Notification

SECTION E: 510(k) SUMMARY

Submitter's Name and Address:

Medtronic Emergency Response Systems
(formerly known as Medtronic Physio-Control)
11811 Willows Road Northeast
Redmond, WA 98052

Contact Person:

Michelle Ackermann
(425) 867-4744

Date Summary Prepared:

June 1st, 2004

Device:

Medtronic LIFEPAK® 12 Defibrillator/Monitor

Classification:

Low Energy DC-Defibrillator: Class II
Automatic External Defibrillator: Class III
Oximeter, Class II

Substantial Equivalence:

The features and functions of the modified LIFEPAK 12 defibrillator are substantially equivalent to the previously cleared LIFEPAK 12 defibrillator, 510(k) numbers K040775 (04/23/04), K033275 (11/06/03), K010918 (03/26/01), K002445 (01/31/01), K990338 (09/01/99), K991910 (06/03/99), K973486 (01/09/98).

Description:

The LIFEPAK 12 defibrillator/monitor is a complete acute cardiac response system, which consists of a battery or auxiliary powered defibrillator (manual or automated), external pacemaker, ECG monitor (3-lead, 5-lead and interpretive 12-Lead), pulse oximeter, noninvasive blood pressure monitor, end-tidal CO₂ monitor, and invasive pressure monitor. Patient data can be transmitted from the LIFEPAK 12 defibrillator to a fax machine, computer, or to a receiving station.

This modification changes the pulse oximetry module and sensors used in the LIFEPAK 12 defibrillator/monitor from Nellcor to Masimo.

Intended Use:

Intended users of the LIFEPAK 12 defibrillator/monitor are Advanced Life Support and Basic Life Support providers in a variety of hospital and pre-hospital settings. The device is used in various areas of the hospital such as critical areas (emergency departments, critical care, operating room, etc.) and general duty floors (e.g. medical/surgical). The device is also used for in and out of hospital transport (air and ground ambulance, in hospital transport, etc.).

Technological characteristics of new and predicate device:

The features and functions of the LIFEPAK 12 defibrillator/monitor are the same as those of the currently marketed LIFEPAK 12 defibrillator/monitor. The modified LIFEPAK 12 uses the same sensors and an updated version of the Masimo SET pulse oximetry module used in the currently marketed LIFEPAK 20 defibrillator/monitor.

Summary of Design Controls:

This 510(k) includes a summary of design control activities and a declaration of conformity to design controls.

The information in this 510(k) notification demonstrates that the modified LIFEPAK 12 defibrillator/monitor is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2004

Medtronic Emergency Response Systems
c/o Ms. Michelle Ackermann
Senior Regulatory Affairs Specialist
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706

Re: K041459

LIFEPAK 12 Defibrillator/Monitor with pulse oximetry feature
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator
Regulatory Class: III (three)
Product Code: MKJ
Dated: June 1, 2004
Received: June 2, 2004

Dear Ms. Ackermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

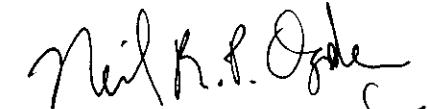
Page 2 – Ms. Michelle Ackermann

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041459

Device Name: LIFEPAK 12 Defibrillator/Monitor

Indications For Use:

AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 12 defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.

Manual Defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Energy delivered in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Noninvasive Pacing is indicated for patients with symptomatic bradycardia or asystole.

12-Lead Electrocardiography is useful in the early detection and prompt treatment of patients with acute myocardial infarction.

Pulse Oximetry is used to check the saturation of oxygen in arterial blood. It is indicated for use in any patient who is at risk of developing hypoxemia.

Mark L. Baker, Jr.
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041459

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K041459

Device Name: LIFEPAK 12 Defibrillator/Monitor

Indications For Use:

Noninvasive Blood Pressure Monitoring is indicated for detection in trends of hypertension or hypotension. These include patient conditions indicated by abnormalities in various physiologic parameters such as shock, evaluation of perfusion during dysrhythmias, major fluid shifts, evaluation of response to fluid therapy, and titration of vasoactive and cardiotonic drugs. Noninvasive blood pressure monitoring may be useful during ECG monitoring or for post-defibrillation recovery analysis.

End-Tidal CO2 monitoring is indicated for detection of trends in the level of expired CO2. It is used for monitoring breathing efficacy in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.

Invasive Pressure Monitoring is indicated for use in measuring arterial, venous, intracranial and other physiological pressures using an invasive catheter system with a compatible transducer.

Neil R. Oyler for BDZ
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K041459

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)